

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ROBIN L. TESKIN
PILLSBURY WINTHROP LLP
1600 TYSONS BOULEVARD
MCLEAN VA 22102

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 23525-012PCT	Date of Mailing (day/month/year) 24OCT2001
International application No. PCT/US01/18774	International filing date (day/month/year) 12 JUNE 2001
Applicant MEDIMMUNE, INC.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.
Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35
For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. **Further action(s):** The applicant is reminded of the following:
 Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.
 Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).
 Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer A. R. SALIMI Telephone No. (703) 308-0196
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 23525-012PCT	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">FOR FURTHER ACTION</div> <div style="font-size: small;">see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</div> </div>	
International application No. PCT/US01/18774	International filing date (<i>day/month/year</i>) 12 JUNE 2001	(Earliest) Priority Date (<i>day/month/year</i>) 21 JUNE 2000
Applicant MEDIMMUNE, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (See Box II).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**.

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/18774

B x I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-6, 45

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/18774**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61K 39/12, 39/00; C12P 21/06; C12N 7/00

US CL : 424/192.1, 204.1; 435/69.1, 235.1, 236

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/192.1, 204.1; 435/69.1, 235.1, 236

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST, DERWENT, MEDLINE, BIOSIS, CAPLUS
search terms: papillomavirus, HPV, late protein, chime?**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,618,536 A (LOWY et al) 08 April 1997, see the claims.	1-6, 45.
Y	US 6,066,324 A (GISSMANN et al) 23 May 2000, see column 3, lines 40-43, and column 4, lines 16-20.	1-6, 45.
Y	US 5,855,891 A (LOWY et al) 05 January 1999, see the claims	1-6, 45.
Y	ZHANG et al. HPV6b virus like particles are potent immunogens without adjuvant in man. Vaccine. 2000, Vol. 18, pages 1051-1058, see the abstract.	1-6, 45.

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

14 AUGUST 2001

Date of mailing of the international search report

24 OCT 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

A. R. SALIMI

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/18774

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

- Group I, claim(s) 1-6, 45, drawn to a chimeric HPV L1 protein capable of eliciting antibody response, and a method of treating a papillomavirus infection. (1st product, and a method of treating)
- Group II, claim(s) 1, 7-9, drawn to chimeric HPV L1 wherein three segments are fused together. (2nd product)
- Group III, claim(s) 1, 10-12, 19, 20, drawn to virus like particles. (3rd product)
- Group IV, claim(s) 1, 13-18, drawn to a gene encoding chimeric HPV protein. (4th product)
- Group V, claim(s) 21-24, 33, drawn to a method of inducing a high titer antibody or cell-mediated response. (2nd method)
- Group VI, claim(s) 25-28, 34, drawn to a method of inducing a high titer antibody or cell-mediated response administering virus like particles. (3rd method)
- Group VII, claim(s) 29-32, 35, drawn to drawn to a method of inducing a high titer antibody or cell-mediated response administering virus like particles with two types of chimeric HPVs. (4th method)
- Group VIII, claim(s) 36-41, 44, drawn to drawn to a method of vaccinating a subject against two types of HPVs. (5th method)
- Group IX, claim(s) 36, 42-43, drawn to a method of vaccinating wherein the vaccine comprises a tribrid type of chimeric L1 molecule. (6th method)
- Group X, claim(s) 46, drawn to a method of treating papillomavirus infection caused by a first HPV type. (7th method)
- Group XI, claim(s) 47, 48, drawn to a method of making a multi-HPV vaccine utilizing PCR. (8th method)
- Group XII, claim(s) 47, 49, drawn to a method of making a multi-HPV vaccine utilizing disassembly and reassembly. (9th method)
- Group XIII, claim(s) 50-54, drawn to a method of diagnosing prior or current papillomavirus infection. (10th method)

The inventions listed as Groups I-XIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Gissmann et al (US patent No. 6,066,324) wherein the reference teaches chimeric or hybrid virus like particles wherein L1 protein can be fused to other proteins of papillomaviruses or of other origins (see column 3, lines 40-43, and column 4, lines 16-20). In addition, Lowy et al (US patent No. 5,618,536) also provides teaching for chimeric L1 papillomavirus (see claim 1). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 as such the restriction is proper.